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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,058

03/15/2005

Wilhelm Scherze

1998.015US1

9013

21186

7590

01/06/2009

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EXAMINER

HOBBS, MICHAEL L

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

01/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,058	Applicant(s) SCHERZE ET AL.	
	Examiner MICHAEL HOBBS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/24/2008 has been entered.
2. Claims 1-20 are pending further action upon the merits.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3, 4, 12, 13, 15, 16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Critser et al. (US 5,700,632) in view of Banes (US 6,586,235).

7. Critser discloses a chamber for the cryo-preservation of cells that for claim 1, includes a body (body 39) or membrane plate with inlets (inlet 29) and outlets (24, 43, 44 & 50) that allow for the flow of a cryo-preservative to flow into the chamber, but is fully capable of allowing nutrient solution and gas to enter the chamber (chamber 40). Critser monitors the temperature within the chamber by a thermocouple (thermocouple 31) that has access to the interior of the body through a channel (Fig. 1a). The chamber is sealed by two glass panes (panes 21 & 22) and a lens (lens 23) of a microscope is positioned to one side of the membrane (membrane 24) and is fully capable of being configured to view the cells on the membrane. The second glass pane (pane 21) is incorporated into the lid (lid 37) or cover of the chamber and is attached in a manner as to be removable (Fig. 2a; col. 8 lines 17-32 & lines 47-47). While the device of Crister is used primarily for the cryo-preservation of cells, the structure

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disclosed can be used for the perfusion and observation of a cell culture. Also, Crister does not specifically state a light source on one side of the membrane, but since a microscope objective is disclosed as the "viewer", it is strongly implied that a light source would be included. Finally, Crister does not specifically state that the membrane is transparent, but it would be within the skills of one of ordinary skill in the art to place a transparent membrane in place of the membrane used by Crister.

8. Banes discloses an apparatus for growing cells that includes inlets and outlets for exchanging culture medium and includes a cover slide for observing the conditions of the culture by a microscope. For claim 1, Banes discloses a membrane (membrane 100) that is made of a transparent material so that the entire apparatus may be placed on a microscope (col. 6 lines 13-15). Banes shows that the problem of lighting and observing with a microscope a cell culture contained on a membrane and that this particular aspect of the problem has been solved. Other methods of solving this problem of observing a cell culture include the use of a video camera or a CCD device. Therefore, following rationale E of *KSR*, 550 US at ___, 82 USPQ2d at 1397, it would have been obvious for one of ordinary skill in the art to try the transparent membrane of Banes within the chamber of Crister with a reasonable expectation of success.

9. With regards to claim 3, the bottom glass pane (pane 22) is against or "abuts" the bottom of the body (body 39) and the lid (lid 37) or cover plate and the lid forms a "chamber cap" with the glass pane and is attached in a fixable manner as shown in Fig. 2a. For claim 4, the top and bottom of the body includes an "opening" for attaching the glass panes (Fig. 2a).

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10. With regards to 12 and 13, Crister is silent regarding the specific material used in constructing the body or membrane plate.

11. For claims 12 and 13, Banes discloses a metal such as stainless steel (col. 4 lines 35-26). Furthermore, stainless steel is known within the art to me a non-toxic material that will not adversely affect the growth of cells. Therefore, for one of ordinary skill in the art, it would have been obvious to try the stainless steel body as suggested by Banes in order to hold the culture medium of Crister with a reasonable expectation of success.

12. With regards to claim 14, Crister discloses more passages above the membrane than below the membrane (Fig. 2a).

13. Critser discloses a chamber for the cryo-preservation of cells that for claim 15, includes a body (body 39) or membrane plate with inlets (inlet 29) and outlets (24, 43, 44 & 50) that allow for the flow of a cryo-preservative to flow into the chamber, but is fully capable of allowing nutrient solution and gas to enter the chamber (chamber 40). Critser monitors the temperature within the chamber by a thermocouple (thermocouple 31) that has access to the interior of the body through a channel (Fig. 1a). The chamber is sealed by two glass panes (panes 21 & 22) and a lens (lens 23) of a microscope is positioned to one side of the membrane (membrane 24) and is fully capable of being configured to view the cells on the membrane. The second glass pane (pane 21) is incorporated into the lid (lid 37) or cover of the chamber and is attached in a manner as to be removable (Fig. 2a; col. 8 lines 17-32 & lines 47-47). While the device of Crister is used primarily for the cryo-preservation of cells, the structure

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disclosed can be used for the perfusion and observation of a cell culture. Also, Crister does not specifically state a light source on one side of the membrane, but since a microscope objective is disclosed as the "viewer", it is strongly implied that a light source would be included. Finally, Crister does not specifically state that the membrane is transparent, but it would be within the skills of one of ordinary skill in the art to place a transparent membrane in place of the membrane used by Crister.

14. Banes discloses an apparatus for growing cells that includes inlets and outlets for exchanging culture medium and includes a cover slide for observing the conditions of the culture by a microscope. For claim 15, Banes discloses a membrane (membrane 100) that is made of a transparent material so that the entire apparatus may be placed on a microscope (col. 6 lines 13-15). Banes shows that the problem of lighting and observing with a microscope a cell culture contained on a membrane and that this particular aspect of the problem has been solved. Other methods of solving this problem of observing a cell culture include the use of a video camera or a CCD device. Therefore, following rationale E of *KSR*, 550 US at ___, 82 USPQ2d at 1397, it would have been obvious for one of ordinary skill in the art to try the transparent membrane of Banes within the chamber of Crister with a reasonable expectation of success.

15. With regards to claim 16, Crister discloses a lens (lens 23) or viewer as was discussed above.

16. For claims 19 and 20, Banes discloses a metal such as stainless steel (col. 4 lines 35-26). Furthermore, stainless steel is known within the art to be a non-toxic material that will not adversely affect the growth of cells. Therefore, for one of ordinary

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skill in the art, it would have been obvious to try the stainless steel body as suggested by Banes in order to hold the culture medium of Crister with a reasonable expectation of success.

17. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crister et al. (US 5,700,632) in view of Banes (US 6,586,235) and in further view of Focht (US 4,974,952).

18. With regards to claims 17 and 18, Crister and Banes imply that a light source on the opposite side of the membrane from the objective, but does not specifically disclose a light source.

19. Focht discloses a live cell culture chamber that includes two glass windows that allows observation of the infusion chamber. For claims 17 and 18, Focht discloses a light source on the second side of the chamber and used to light the inside of the chamber (Fig. 1). Also, the light is fully capable of lighting the chamber through the membrane. Moreover, it would be obvious to one of ordinary skill in the art to have the light source suggested by Focht on the opposite side of the membrane of Crister and Banes in order to illuminate the cells on the membrane.

20. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crister et al. (US 5,700,632) in view of Banes (US 6,586,235) and in further view of Shanks (US 4,810,658).

21. Crister and Banes are silent regarding the glass panes being a sapphire glass.

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22. Shanks discloses a photometric instrument that is used for optical analysis of samples on a microscope slide. Furthermore, for claim 5, Shanks discloses a slide that is made of glass, silica, inorganic crystal (e.g. sapphire) or a plastic material (col. 3 lines 35-38). Therefore, it would have been obvious to one of ordinary skill in the art to employ the sapphire slide as suggested by Shanks within the culture chamber of Crister and Banes in order to allow light to pass through the sample for optical testing. The suggestion for doing so at the time would have been in order to allow light from the liquid sample to emerge at different angles off-axis from the slide for the optical testing (Abstract).

23. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crister et al. (US 5,700,632) in view of Banes (US 6,586,235) and in further view of Machemer et al. (J. Comp. Physiol. A (1991) 168: 1-12).

24. Both Crister and Banes disclose a membrane, but are silent regarding a biofoil.

25. Machemer discloses studying gravikinesis in paramecium by optically monitoring the cells in a plexi-glass chamber that includes bores for administering an experimental solution and a gas-permeable membrane. For claim 11, Machemer discloses using a gas-permeable transparent biofoil that is between the well and cover (Fig. 6c; section: Materials and methods paragraph 6 page 6 (chamber)). The use of this type of membrane was therefore known at the time of the invention to one of ordinary skill in the art. Therefore, one of ordinary skill in the art would have found it

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obvious to try the biofoil as suggested by Machemer to cultivate the cells of Cristner and Banes with a reasonable expectation of success.

26. Claims 1 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minuth (US 5,665,599) in view of Banes (US 6,586,235) and in further view of Focht (US 4,974,952).

27. For claim 1, Minuth discloses a chamber for cultivating cells that includes a cell carrier (17) or membrane plate that divides the chamber into two portions. Also, the chamber includes conduits (21, 22) for delivering nutrient media to the cells and a sensor (23) is placed within the cell chamber. Furthermore, the chamber includes a glass plate(13) which is located on one side of the cell carrier plate and above the microscope objective (14). On the other side of the cell carrier plate is another thin disk (13a) which covers the aperture and is also made out of glass (col. 3 lines 39-40).

While not specifically teaching that a light source is on the other side of the device, it is implied within the teachings of that a light source would be opposite of the microscope objective in order to illuminate the cells on the carrier plate.

28. Banes discloses an apparatus for growing cells that includes inlets and outlets for exchanging culture medium and includes a cover slide for observing the conditions of the culture by a microscope. For claim 1, Banes discloses a membrane (membrane 100) that is made of a transparent material so that the entire apparatus may be placed on a microscope (col. 6 lines 13-15). Banes shows that the problem of lighting and observing with a microscope a cell culture contained on a membrane and that this

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particular aspect of the problem has been solved. Other methods of solving this problem of observing a cell culture include the use of a video camera or a CCD device. Therefore, following rationale E of *KSR*, 550 US at ____, 82 USPQ2d at 1397, it would have been obvious for one of ordinary skill in the art to try the transparent membrane of Banes within the chamber of Minuth with a reasonable expectation of success.

29. Focht discloses a live cell culture chamber that includes two glass windows that allows observation of the infusion chamber. For claim 1, Focht discloses a light source on the second side of the chamber and used to light the inside of the chamber (Fig. 1). Also, the light is fully capable of lighting the chamber through the membrane. Moreover, it would be obvious to one of ordinary skill in the art to have the light source suggested by Focht on the opposite side of the membrane of Minuth and Banes in order to illuminate the cells on the membrane.

30. For claim 6, the carrier plate (17) is connected to a ring (16) that is held in place by sealing ring (15, 15a) or retaining ring for holding the carrier plate (col. 2 lines 46-49). Regarding claim 7, Minuth teaches that a seal (18,18a) is placed on top of the glass plate (13a) and this seal is fully capable of aseptically sealing the chamber. With regards to claim 8, Minuth also includes conduits (22) that make it possible to feed or drain liquid or gaseous media from the chamber (col. 3 lines 16-22). These conduits are fully capable of continuously feeding gas or liquid media to the chamber.

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31. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minuth (US 5,665,599) in view of Banes (US 6,586,235) and in further views of Focht (US 4,974,952) and Loeffler et al. (US 6,673,620).

32. For claim 9, Minuth teaches that the chamber or interior can be heated (col. 3 lines 54-59), but does not teach that the heater is integrated or electrical. Banes and Focht are silent regarding a heater.

33. Loeffler teaches an in situ hybridization (ISH) cell that is used to observe fluid exchange on a microscope slide. For claim 9, Loeffler discloses that a heater plate is underneath the microscope slide (Fig. 1 elements 7 & 9) that can be used to heat the sample on the slide (col. 6 lines 5-8). The heater plate protects the heating element from any spillage of the liquid from the slide (col. 6 lines 11-12) and with the heat transfer into the fluid observation system being through the heating plate (col. 6 lines 13-14), thus the heating plate is integrated into the microscope slide. For claim 10, the heater plate of Loeffler is connected to a resistive heating (where resistive heating is being interpreted to be electrical heating) element (col. 6 line 10) that facilitates even heat transfer across the plate. At the time of the invention, it would have been obvious to one of ordinary skill in the art to employ the heater plate and heating element as suggested by Loeffler within the teachings of Minuth, Banes and Focht in order to heat the sample within the chamber. The suggestion for doing so at the time would have been in order to stabilize the temperature around a desired mean temperature (col. 6 lines 16-17).

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34. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierson et al. (US 6,498,862 B1) in view of Focht (US 4,974,952).

35. Pierson discloses a device for the evaluation of biofilms which is fully capable of cultivating cells and for claim 1 includes a transparent membrane (membrane 1) or membrane plate that is sandwiched between two glass slides (slides 2 & 3) and held together with a bottom and a top bracket or cover plate (bracket 4). Furthermore, the cells on the membrane are observed by a microscope (microscope 26) or viewer (col. 6 lines 12-15 & 30-35). Pierson does not specifically disclose a light source on the other side of the plate, but such a light source would normally be part of an observation system such as disclosed by Pierson.

36. Focht discloses a live cell culture chamber that includes two glass windows that allows observation of the infusion chamber. For claim 1, Focht discloses a light source on the second side of the chamber and used to light the inside of the chamber (Fig. 1). Also, the light is fully capable of lighting the chamber through the membrane. Moreover, it would be obvious to one of ordinary skill in the art to have the light source suggested by Focht on the opposite side of the slide in order to illuminate the cells of Pierson with a reasonable expectation of success.

37. With regards to claim 2, the slide of Pierson is adjacent or “abuts” the membrane (Fig. 3a).

Response to Arguments

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38. Applicant's arguments, see page 8 paragraph 5 and page 2 lines 13-14, filed 11/24/2008, with respect to the rejection(s) of claim(s) 1-4 and 6-8 under 35 USC 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found references Crister et al. (US 5,700,632) and Machemer et al. (J. Comp. Physiol. A (1991) 168: 1-12) and a new interpretation of Minuth, Banes and Loeffler. Crister discloses a chamber for the observation of cells that reads on the structure of the claimed invention of the instant application and Machemer discloses using a biofoil for the testing of *Paramecium*.

Conclusion

39. Claims 1-20 are cancelled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/William H. Beisner/
Primary Examiner, Art Unit 1797

/M.L.H./
MICHAEL HOBBS
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